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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,254	12/27/2000	Siamak Tabibzadch	0152.00384	8450

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/674,254

Applicant(s)

TABIBZADEH, SIAMAK

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 41-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 70 is/are allowed.
- 6) ☐ Claim(s) 41-69 and 71-80 is/are rejected.
- 7) ☐ Claim(s) 63 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-40 have been canceled.

New Claims 41-80 have been added.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2003.

#### ***Allowable Subject Matter***

3. Claim 70 defines over the prior art of record and is therefore allowed.

#### ***Priority***

4. Priority under 35 U.S.C. 119(e) based upon a previously filed application, is acknowledged.

#### ***Information Disclosure Statement***

5. The information disclosure statement filed August 8, <sup>2003</sup><sub>2003</sub> has been considered.

#### ***Rejections Withdrawn***

6. As all prior claims have been canceled, all prior rejections are herein withdrawn.

***New Claims/New Combination of Claim Limitations/New Grounds of Rejection***

***Claim Objections***

7. Claim 63 is objected to because of the following informalities: Claim 63 recites the term “menometrorrahgia”; this term is mis-spelled and should be –menometrorrahagia--. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

8. The claimed invention is directed to non-statutory subject matter. Claims 72-73 are directed to methods, which increase or decrease the level of expression of ebaF (nucleic acid) or EBAF (protein), but does not administer, provide any specific means for the accomplishment of the intended use of the claimed methods , which assert that with an increase of expression fertility is decreased, and with a decrease of expression fertility is increased. As a females normal cycle evidences natural increases and decreases in the level of expression of ebaF and EBAF in order to maintain a healthy uterus for conception and to maintain receptivity over the life of the female, the instantly claimed methods which do not provide any means for effecting the increase or decrease and therefore read on a natural process. The claimed methods do not show the hand of man and therefore read on natural processes and methods of increasing and decreasing receptivity, which are provided in nature to maintain fertility over the normal life cycle of a female.

***Claim Rejections - 35 USC § 112***

9. Claims 72-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and/or use the invention. Claims 72-73 are directed to methods, which increase or decrease the level of expression of ebaf (nucleic acid) or EBAF (protein), but are not enabled for the utilization of any means or methods for increasing or decreasing ebaf or EBAF expression or biological activity. No specific reagents are recited in the claims, and any reagent would not serve to accomplish the claimed methods, which require a specific effect, either, an increase or decrease in ebaf expression or biological activity of EBAF. The instantly claimed genus of methods is not enabled for embodiments not described. The methods of claims 72 and 73 accomplish the recited intended use without administration of any product or composition. The instant specification does not teach, suggest nor provide guidance for the accomplishment of the claimed methods which only comprise a single methods step of increasing or decreasing the level of expression or activity of ebaf or EBAF without the administering of a composition that effects expression or biological activity. The claimed methods are not enabled.

10. Claims 72-73 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 72 recites the phrase “decreasing the level of expression” of an ebaf nucleic acid or protein, but means for decreasing the level of expression have not been provided or administered. The method is incomplete.

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Claim 73 recites the phrase "increasing the level of expression" of ebaf nucleic acid or protein, but means for decreasing the level of expression have not been provided or administered. The method is incomplete.

***Claim Rejections - 35 USC § 102***

**Please Note:** The term "having" is being read to mean "comprising".

11. <sup>71-72</sup> Claims 41-69, ~~71-72~~ are rejected under 35 U.S.C. 102(e) as being anticipated by Tabibzadeh et al (US Pat. 5,916,751; effective filing date Aug. 27, 1996), in light of Kothapalli et al (reference incorporated by reference into US Pat. 5,916,751, col. 4, lines 6-15, and teaches ebaf is associated with endometrial bleeding.)

(Instant claim 41, 54) Tabibzadeh et al disclose the instantly claimed invention directed to a method of detecting or diagnosing endometrial irregularity, receptivity (normal levels, see col. 4, line 46 endometrium) in a female, the method comprising the step of:

Screening endometrial tissue or blood for abnormal levels of ebaf nucleic acid or protein (see Figures 1-2; col. 3, lines 65-67; col. 4, lines 6-15, col. 4, lines 51-67; col. 5, lines 1-3; col. 5, lines 27-39).

(Instant claim 42, 58) Northern blot (see col. 5, lines 40-col. 6, lines 1-67; Example 2, col. 8, lines 29-46);

(Instant claim 43, 55, 59) protein determined by antibody or antisera (see col. 9, section III Immunoassay, col. 9, lines 51-67 through col. 12, line 23) polyclonal or monoclonal antibodies (see col. 9, line 56); antisera col. 10, lines 52-62)

(Instant claim 44, 60) Western Blot (see claim 9, line 64);

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(Instant claim 45, 56) Immunohistochemical (see col. 10, line 29);

(Instant claim 46-48) infertility, specifically endometriosis (col. 5, lines 1-3), a type of abnormal uterine bleeding. (col. 5, lines 2-3).

(Instant claim 57) PCR (see col. 9, lines 1-51);

(Instant claims 61-63 ) A method that comprises the steps of ;

determining ebaf nucleic acid or protein in a endometrial or blood sample (see examples 1-3, col. 8-12; also see col. 4, lines 6-15); and

correlating (determined level to be normal or abnormal relative to normal levels, see col. 4, lines 60-61 “presence of a mucinous adenocarcinoma of the colon or ovary) the level with normal levels (normal levels of ebaf in endometrium, and is present in blood sample, which comprises serum, see col. 4, line 46, line 52 ) to provide a diagnosis or prognosis of infertility (adenocarcinoma of the ovary is a condition that is included in the broad definition of infertility); (see col. 9, lines 53-63 comparison between the basal normal level and an abnormal level).

(Instant claim 49-53) diagnostic tool that is an antibody or nucleic acid or immunohistochemical stain to determine the presence of ebaf nucleic acid or EBAF protein (see col. 5, lines 25-39; col. 10, lines 37-40).

(Instant claim 64, 66, 69) An isolated antibody that binds to the protein encoded by ebaf nucleic acid (see col. 5, lines 27-30) or binds to a peptide that comprises SEQ ID NO 3 (in light of Kothapalli et al who shows the amino acid sequence of the protein encoded by

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SEQ ID NO. 1 the antibodies of Tabibzadeh et al discloses an antibody body that binds to any one of the domains of ebaf (see col. 10, lines 52-62).

(Instant claim 65, 67) a monoclonal antibody (see col. 9, line 56; Harlow, 1988, col. 10, lines 42-58).

(Instant claim 68) An isolated antiserum or antisera that binds to the protein encoded by ebaf nucleic acid (see col. 10, lines 52 and 57 "antiserum").

(Instant claim 71) a protein encoded by an ebaf nucleic acid in a carrier (see col. 5, lines 27-30; isolated ebaf protein in a bodily fluid; a chimeric fusion protein or synthesized peptide of one of the three isoforms of ebaf (see col. 10, lines 53-55).

***Claim Rejections - 35 USC § 103***

12. Claims 74-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabibzadeh et al (US Pat. 5,916,751).

Tabibzadeh et al disclose the utilization of nucleic acid detection and protein detection kits (see col. 6, line 7; col. 10, line 5; col. 11, line 17) for the determination of ebaf nucleic acid expression and/or EBAF protein/peptide biological activity in a biological sample (blood or endometrium), wherein a nucleic acid probe, primer, antibody, or antiserum (see cols. 8-12) are utilized in the methods of determination. Tabibzadeh et al differs from the instantly claimed invention by failing to show the incorporation of the ebaf nucleic acid probe or primer and/or the EBAF protein/peptide specific polyclonal or monoclonal antibody, or antiserum into kit form.



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It would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate the necessary reagents for the determination, detection or diagnosis of an ebaf or EBAF condition (see col. 3, lines 66-67 and col. 4, lines 1-5), which would include an antibody, or a monoclonal antibody that binds EBAF, or an antibody or monoclonal antibody that binds a peptide comprising SEQ ID No 3 (see col. 5, lines 27-30; col. 9, lines 53-67, col. 10, lines 1-67, col. 11-12), because Tabibzadeh et al teach methods that are “accurate, dependable, inexpensive, and do not possess the shortcomings of the prior art methods (see col. 3, lines 61-62)” for determining the presence or absence of a normal or abnormal level of ebaf or EBAF and formulation of the needed reagents into kit form provide means for ready determination of EBAF “using the kit (see col. 11, line 17).

Tabibzadeh et al teach means, methods, probes. Primers, antibodies, and assays using said probes, primers and antibodies for the termination of ebaf or EBAF in a biological sample, and the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining kits that comprise a nucleic acid, a peptide, an antibody or antisera to EBAF because Tabibzadeh et al teach the utilization of kits for the determination of normal and abnormal levels of EBAF, and teach and suggest the utilization of both polyclonal and monoclonal antibodies, and antisera, as well as probes and primers for the determination of the presence and amount of ebaf or EBAF associated with pathological conditions effecting human fertility and receptivity.

In the absence of a showing of unexpected results, Tabibzadeh et al obviates the instantly claimed invention.

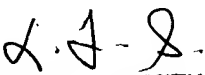
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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703) 308-7543. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703)308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Vgp  
October 20, 2003

  
**LYNETTE R. F. SMITH**  
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